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8. SUMMARY OF 510 K SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K011353.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:
27 April 2001

Contact Person:
Edward Tung, Ph.D.
Director of Regulatory Affairs

Product Name:
ACON® OPI One Step Opiates Test Strip
ACON® OPI One Step Opiates Test Device

Common Name:
Immunochromatographic test for the qualitative detection of morphine and opiates in urine.

Device Classification:
The ACON OPI One Step Opiates Test Strip and ACON OPI One Step Opiates Test Device are similar to other FDA-cleared devices for the qualitative detection of opiates in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862.3650). Opiates test systems have been classified as Class II devices, moderate complexity.

Classification Name:
Opiates test system

Intended Use:
The ACON® OPI One Step Opiates Test Strip and ACON® OPI One Step Opiates Test Device are rapid chromatographic immunoassays for the qualitative detection of opiates in human urine at a cut-off concentration of 2000 ng/ml. They are intended for professional and point of care use.

Description:
The ACON OPI One Step Opiates Test Strip and ACON OPI One Step Opiates Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of opiates in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes a monoclonal antibody to selectively detect elevated levels of opiates in urine at a cut-off concentration of 2000 ng/ml. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug negative urine specimen will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Predicate Device:
LifeSign Status DS™ OPI One-Step Opiates Test

510(k) Number 981771

Distributor:
LifeSign, LLC
71 Veronica Avenue
Somerset, New Jersey 08873

Comparison to a Predicate Device:
A summary comparison of the features of the ACON OPI One Step Opiates Test Strip and ACON OPI One Step Opiates Test Device and the LifeSign Status DS™ OPI One-Step Opiates Test is shown below.

- Both tests are assays intended for the qualitative detection of morphine, codeine and morphine derivatives in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of morphine, codeine and morphine derivatives with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen / antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off concentration of 2000 ng/ml.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 specimens. This evaluation compared the results of the ACON OPI One Step Opiates Test Strip and the ACON OPI One Step Opiates Test Device and the LifeSign Status DS™ OPI One-Step Opiates Test to the customary Gas Chromatography/Mass Spectrometry analysis technique. The data from this study yielded the following results:

ACON OPI One Step Opiates Test Strip compared to the LifeSign Status DS™ OPI One-Step Opiates Test:

Positive Agreement: 150 / 150 = 100%
Negative Agreement: 150 / 150 = 100%
Overall Agreement: 300 / 300 = 100%

ACON OPI One Step Opiates Test Device compared to the LifeSign Status DS™ OPI One-Step Opiates Test:

Positive Agreement: 150 / 150 = 100%
Negative Agreement: 150 / 150 = 100%
Overall Agreement: 300 / 300 = 100%

ACON OPI One Step Opiates Test Strip compared to GC/MS:

Sensitivity:	134 / 134 = 100%	(97% – 99%) *
Specificity:	150 / 166 = 90%	(85% – 94%) *
Accuracy:	278 / 300 = 95%	(89% - 95%) *
PPV (+):	134 / 150 = 89%	(83% - 94%) *
NPV (-):	150 / 150 = 100%	(98% - 99%) *

ACON OPI One Step Opiates Test Device compared to GC/MS

Sensitivity:	134 / 134 = 100%	(97% - 99%) *
Specificity:	150 / 166 = 90%	(85% – 94%) *
Accuracy:	278 / 300 = 95%	(89% - 95%) *
PPV (+):	134 / 150 = 89%	(83% - 94%) *
NPV (-):	150 / 150 = 100%	(98% - 99%) *

* Denotes 95% confidence intervals

Conclusion:

These studies demonstrate the substantial equivalency between the ACON OPI One Step Opiates Test Strip and ACON OPI One Step Opiates Test Device with the LifeSign Status DS™ OPI One-Step Opiates Test, which is already being marketed in the United States. In addition, it is demonstrated that these tests are safe and effective in detecting morphine (and opiates) at a concentration of 2000 ng/ml. It is also demonstrated that these tests are suitable for professional and point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 0 2001

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: 510(k) Number: K011353
Trade/Device Name: ACON® OPI One Step Opiates Test Strip and ACON® OPI One Step Opiates Test Device
Regulation Number: 862.3650
Regulatory Class: Class II
Product Code: DJG
Dated: July 5, 2001
Received: July 9, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: **K011353**

Device Name: ACON® OPI One Step Opiates Test Strip
ACON® OPI One Step Opiates Test Device

Indications for Use: The ACON OPI One Step Opiates Test Strip and ACON OPI One Step Opiates Test Device are rapid chromatographic immunoassays for the qualitative detection of opiates in human urine at a cut-off concentration of 2,000 ng/ml. It is intended for professional and professional point of care use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011353

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-The-Counter Use_____

(Per 21 CFR 801.109)